

xF+ Validation

The non-invasive Tempus xF+ liquid biopsy assay detects cell-free DNA (cfDNA) in blood specimens of advanced solid tumor patients.

The assay covers clinically relevant exons and select non-coding regions in 523 genes (including 19 genes for insight into HRR gene-mutated mCRPC) spanning ~1.8 Mb of genomic space and is capable of detecting mutations in four variant classes: single nucleotide variants (SNVs) and insertion-deletions (INDELs) in 523 genes; copy number gains (CNGs) in 7 genes; and gene rearrangements in 10 genes (including NTRK 1/2/3 and FGFR 1/2/3). 114 genes will be sequenced with enhanced coverage and lower limit of detection (0.25% VAF for SNVs). Select variants may be reported at VAFs lower than 0.25% at pathologist discretion.¹ Blood Tumor Mutational Burden (bTMB) as well as detected Microsatellite Instability High (MSI-H) will be reported. Tempus xF+ is designed to capture clinically relevant biomarkers for solid tumors.

CAP/CLIA validation of the Tempus xF+ panel at Tempus' Chicago, Illinois laboratory focused on the detection of actionable oncologic variants including resistance mutations in plasma. The assay requires two 8.5 mL Streck tubes of peripheral blood. Clinical sequencing is performed to >5000x and >1500x unique coverage for enhanced and additional regions, respectively. Performance specifications are listed in the table below. These results establish, as shown in the table, high sensitivity and specificity for the Tempus xF+ assay.

Not intended for:

- Hematologic malignancies
- Early stage (stage I/II) cancers
- Primary CNS malignancies

xF+ PERFORMANCE SPECIFICATIONS

Variant Class	VAF	Sensitivity	Specificity	LOD
SNVs (Enhanced)	≥0.25%	>99.9%	>99.9%	0.25%
SNVs (Non-Enhanced)	≥1%	>99.9%	>99.9%	1%
INDELs (Enhanced)	≥0.5%	98.0%	>99.9%	0.5%
INDELs (Non-Enhanced)	≥2%	87.5%	>99.9%	2%
CNGs	≥1%	>99.9%	92.0%	1%
Rearrangements	≥1%	96.8%	>99.9%	1%
MSI-H Status	—	90.0%	>99.9%	—
bTMB	—	78.5%	>99.9%	—

¹ Sensitivity of detecting variants with VAFs lower than 0.25% may be lower than listed.

xF+ Gene List

ABCC3 ²	BIRC3 ²	CREBBP ²	ERBB4 ²	FLT1 ²	ID3 ²	KRAS ¹	MYB ²	PHLPP2 ²	RAD51C ¹	SMARCB1 ²	TSC1 ¹
ABL1 ¹	BLM ²	CRKL ¹	ERCC2 ²	FLT3 ¹	IDH1 ¹	LATS1 ²	MYC ^{1,4}	PIAS4 ²	RAD51D ²	SMC1A ²	TSC2 ¹
ABL2 ²	BMPR1A ²	CSF1R ²	ERCC3 ²	FLT4 ²	IDH2 ¹	LCK ²	MYCL ²	PIK3C2B ²	RAD52 ²	SMC3 ²	TSHR ²
ABRAXAS1 ²	BRAF ^{1,3}	CSF3R ²	ERCC4 ²	FOLH1 ²	IFNA21 ²	LMO1 ²	MYCN ¹	PIK3C2G ²	RAD54L ²	SMO ¹	TYMS ²
ACVR1 ²	BRCA1 ¹	CTC1 ²	ERCC6 ²	FOXA1 ²	IFNAR1 ²	LRP1B ²	MYD88 ¹	PIK3CA ¹	RAF1 ¹	SNCAIP ²	TYRO3 ²
ACVR1B ²	BRCA2 ¹	CTCF ²	ERG ²	FOXO1 ²	IFNAR2 ²	LTK ²	NBN ²	PIK3CB ²	RARA ²	SOCS1 ²	U2AF1 ²
AJUBA ²	BRD4 ²	CTLA4 ²	ERRFI1 ¹	FOXO2 ²	IFNG ²	LYN ²	NCOA2 ²	PIK3CD ²	RASA1 ²	SOS1 ²	UGT1A1 ²
AKT1 ¹	BRIP1 ²	CTNNA1 ²	ESR1 ¹	FOXO3 ²	IFNGR1 ²	LZTR1 ²	NCOR1 ²	PIK3CG ²	RB1 ¹	SOX2 ²	VEGFA ¹
AKT2 ¹	BTG1 ²	CTNNB1 ¹	ETNK1 ²	FOXO3 ²	IFNGR2 ²	MAF ²	NF1 ¹	PIK3R1 ¹	RBM10 ²	SOX9 ²	VHL ¹
AKT3 ²	BTG2 ²	CUL3 ²	ETV1 ²	FRS2 ²	IFNW1 ²	MALT1 ²	NF2 ¹	PIK3R2 ²	RECQL4 ²	SPEN ²	VSIR ²
ALK ^{1,3}	BTK ¹	CUL4A ²	ETV4 ²	FUBP1 ²	IGF1 ²	MAP2K1 ¹	NFE2L2 ¹	PIM1 ²	REL ²	SPOP ¹	WEE1 ²
ALOX12B ²	CALR ²	CUX1 ²	ETV5 ²	GABRA6 ²	IGF1R ²	MAP2K2 ¹	NFKBIA ²	PLCG1 ²	RET ^{1,3}	SRC ²	WNK1 ²
AMER1 ²	CARD11 ²	CXCR4 ²	ETV6 ²	GALNT12 ²	IKBKE ²	MAP2K4 ²	NKX2-1 ²	PLCG2 ²	RHEB ¹	SRSF2 ²	WRN ²
APC ¹	CARM1 ²	CYLD ²	EWSR1 ²	GATA1 ²	IKZF1 ²	MAP3K1 ²	NOTCH1 ¹	PMS1 ²	RHOA ¹	STAG2 ²	WT1 ²
APLN ²	CASP8 ²	CYP17A1 ²	EZH2 ¹	GATA3 ¹	IL10RA ²	MAP3K13 ²	NOTCH2 ²	PMS2 ¹	RICTOR ²	STAT3 ²	XBP1 ²
AR ¹	CBFB ²	CYSLTR2 ²	EZR ²	GATA4 ²	IL32 ²	MAP3K21 ²	NOTCH3 ²	POLA1 ²	RIT1 ¹	STAT5B ²	XPA ²
ARAF ¹	CBL ²	DAXX ²	FAM46C ²	GATA6 ²	IL6R ²	MAP3K7 ²	NOTCH4 ²	POLD1 ²	RNF43 ¹	STAT6 ²	XPC ²
ARFRP1 ²	CCND1 ¹	DBP2 ²	FANCA ²	GID4 ²	IL7R ²	MAPK1 ¹	NPM1 ¹	POLE ²	ROS1 ^{1,3}	STK11 ¹	XPO1 ²
ARID1A ¹	CCND2 ¹	DDR1 ²	FANCC ²	GLI2 ²	IMPDH1 ²	MAPK3 ¹	NQO1 ²	POLQ ²	RPS6KB1 ²	SUFU ²	XRCC1 ²
ARID1B ²	CCND3 ¹	DDR2 ¹	FANCD2 ²	GNA11 ¹	ING1 ²	MAX ²	NRAS ¹	POT1 ²	RPTOR ²	SUZ12 ²	XRCC2 ²
ARID2 ²	CCNE1 ^{1,4}	DDX3X ²	FANCE ²	GNA13 ²	INPP4B ²	MC1R ²	NRG1 ²	PPARG ²	RRM1 ²	SYK ²	YEATS4 ²
ASNS ²	CD22 ²	DDX41 ²	FANCG ²	GNAQ ¹	INSR ²	MCL1 ²	NSD1 ²	PPM1D ²	RSF1 ²	TBX3 ²	ZFH3 ²
ASXL1 ²	CD274(PD-L1) ^{1,4}	DEPTOR ²	FANCI ²	GNAS ¹	IRF1 ²	MDM2 ^{1,4}	NSD2 ²	PPP2R1A ²	RSP02 ²	TCF7L2 ²	ZMYM3 ²
ATM ¹	CD70 ²	DICER1 ²	FANCL ²	GNAS ¹	IRF2 ²	MDM4 ²	NSD3 ²	PPP2R2A ²	RUNX1 ²	TEK ²	ZNF217 ²
ATR ¹	CD74 ²	DIS3 ²	FANCM ²	GPS2 ²	IRF4 ²	MED12 ²	NT5C2 ²	PPP6C ²	RXRA ²	TERC ²	ZNF703 ²
ATRX ²	CD79A ²	DNMT1 ²	FAS ²	GREM1 ²	IRS2 ²	MEF2B ²	NTRK1 ^{1,3}	PRDM1 ²	SDC4 ²	TERT ¹	ZNF750 ²
AURKA ²	CD79B ²	DNMT3A ²	FAT1 ²	GRIN2A ²	JAK1 ¹	MEN1 ²	NTRK2 ^{1,3}	PREX2 ²	SDHA ¹	TET2 ²	ZNRF3 ²
AURKB ²	CDC73 ²	DOT1L ²	FBXW7 ¹	GRM3 ²	JAK2 ¹	MERTK ²	NTRK3 ^{1,3}	PRKACA ²	SDHAF2 ²	TFEB ²	ZRSR2 ²
AURKC ²	CDH1 ¹	DPYD ²	FCGR2A ²	GSK3B ²	JAK3 ¹	MET ^{1,4}	NUTM1 ²	PRKAR1A ²	SDHB ²	TGFB1 ²	
AXIN1 ²	CDK12 ¹	EBF1 ²	FCGR3A ²	GSTP1 ²	JUN ²	MITF ²	P2RY8 ²	PRKCI ²	SDHC ²	TGFB1 ²	
AXIN2 ²	CDK4 ¹	EED ²	FGF10 ²	H3F3A ²	KAT6A ²	MKNK1 ²	PAK1 ²	PRKN ²	SDHD ²	TGFB2 ²	
AXL ²	CDK6 ¹	EEF2 ²	FGF12 ²	HAVCR2 ²	KDM5A ²	MLH1 ¹	PALB2 ¹	PTCH1 ¹	SETBP1 ²	TIGIT ²	
B2M ¹	CDK8 ²	EGFR ^{1,4}	FGF14 ²	HDAC1 ²	KDM5C ²	MLH3 ²	PALLD ²	PTEN ¹	SETD2 ²	TIPARP ²	
BAP1 ¹	CDK9 ²	EGLN1 ²	FGF19 ²	HDAC2 ²	KDM5D ²	MPL ¹	PARP1 ²	PTK2 ²	SF3B1 ²	TMEM127 ²	
BARD1 ²	CDKN1A ²	EIF1AX ²	FGF23 ²	HGF ²	KDM6A ²	MRE11 ²	PARP2 ²	PTPN11 ¹	SGK1 ²	TMPRSS2 ²	
BAX ²	CDKN1B ²	ELF3 ²	FGF3 ²	HIF1A ²	KDR ¹	MS4A1 ²	PARP3 ²	PTPN13 ²	SIRPA ²	TNFAIP3 ²	
BCL2 ²	CDKN2A ¹	EMSY ²	FGF4 ²	HIST1H3B ²	KEAP1 ¹	MSH2 ¹	PAX5 ²	PTPRD ²	SLC34A2 ²	TNFRSF14 ²	
BCL2L1 ²	CDKN2B ²	EP300 ²	FGF6 ²	HLA-B ²	KEL ²	MSH3 ¹	PBRM1 ¹	PTPRO ²	SLC9A3R1 ²	TNFRSF17 ²	
BCL2L11 ²	CDKN2C ²	EPCAM ²	FGFR1 ^{1,3}	HNF1A ¹	KIT ¹	MSH6 ¹	PDCD1 ²	PTPRT ²	SLFN11 ²	TOP1 ²	
BCL2L2 ²	CEBPA ²	EPHA2 ²	FGFR2 ^{1,3}	HNF1B ²	KLF4 ²	MST1R ²	PDCD1LG2 ¹	QKI ²	SLIT2 ²	TOP2A ²	
BCL6 ²	CHD4 ²	EPHA3 ²	FGFR3 ^{1,3}	HOXB13 ²	KLHL6 ²	MTAP ²	PDGFRA ¹	RAC1 ²	SMAD2 ²	TP53 ¹	
BCLAF1 ²	CHEK1 ²	EPHB1 ²	FGFR4 ¹	HRAS ¹	KLLN ²	MTHFR ²	PDGFRB ¹	RAD21 ²	SMAD3 ²	TP53BP1 ²	
BCOR ²	CHEK2 ¹	EPHB4 ²	FH ²	HSD3B1 ²	KMT2A ¹	MTOR ¹	PDK1 ²	RAD50 ²	SMAD4 ¹	TP63 ²	
BCORL1 ²	CIC ²	ERBB2(HER2) ^{1,4}	FHIT ²	HSP90AA1 ²	KMT2C ²	MUC16 ²	PHGDH ²	RAD51 ²	SMARCA2 ²	TRAF3 ²	
BCR ²	CKS1B ²	ERBB3 ¹	FLCN ²	HSPH1 ²	KMT2D ²	MUTYH ²	PHLPP1 ²	RAD51B ²	SMARCA4 ²	TRAF7 ²	

GENE REARRANGEMENTS

ALK, BRAF, FGFR1, FGFR2, FGFR3, NTRK1, NTRK2, NTRK3, RET, ROS1

COPY NUMBER GAINS

CCNE1, CD274(PD-L1), EGFR, ERBB2(HER2), MDM2, MET, MYC

¹ Enhanced SNV/Indel ² Non-Enhanced SNV/Indel ³ Fusion ⁴ CNG